

68959-7

5/6/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

May 6, 2013

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Micah T. Reynolds
Regulatory Consultant to Veltek Associates, Inc.
c/o Technology Sciences Group Inc.
1150 18th Street N.W. Suite 1000
Washington, DC 20036

Subject: **HYPO-CHLOR® 0.25 %**
EPA Registration No. 68959-7
Application Date: December 12, 2012
Receipt Date: December 14 2012

Dear Mr. Reynolds:

The following amendment, submitted in connection with registration under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is **acceptable**.

Proposed Amendment:

Registrant has revised their Basic and Alternate Confidential Statement of Formula in response to the Agency deficiency letter of February 05, 2013

General Comment:

Based upon a review of the material submitted, the CSFs dated February 12, 2013 noted above are **acceptable**. A copy of the CSFs will be placed in the record for the product. A stamped copy of the accepted label is enclosed dated 05/6/13. Submit two (2) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, you may contact Glen McLeod by telephone at (703) 347-0181 or by e-mail at mcleod.glen@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Mendelsohn", with a long horizontal flourish extending to the right.

Michael Mendelsohn
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

HYPO-CHLOR 0.25% ® MC

For Use in Clean Rooms and Controlled Areas
Hard Surface Disinfectant
Aseptically Filtered at 0.2 µm

Active Ingredients:

Sodium Hypochlorite CAS# 7681-52-9.....0.25%

Other Ingredients:

*Water99.75%

Total100.00%

*USP Water for Injection

KEEP OUT OF REACH OF CHILDREN WARNING

[See [other][side][back][panel][package insert] for [first aid][directions for use] [and additional precautions].]

Net Contents: (US XXoz or gallons)

EPA Reg. No.: 68959-7

EPA Est. No.: 68959-PA-001

Manufactured by:

Veltek Associates, Inc.

15 Lee Blvd.

Malvern PA 19355 – 1234 USA

Tel: 610-644-8335

Fax: 610-644-8336

www.sterile.com

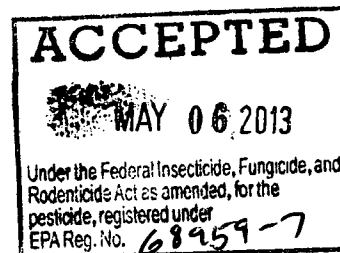
In Canada, distributed by:

Canada Clean Room (CCR) www.ccrkanata.com

200 Terrance Matthews

Kanata, On. K2M 2C6

Made in USA VAI {corporate logo}



FIRST AID

If in Eyes: If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glassful of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

EMERGENCIES: For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada in English, French, and Spanish (and 23 other languages) call CARECHEM24 toll free at 866-928-0789.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

PHYSICAL AND CHEMICAL HAZARDS: Contact with acid releases toxic chlorine gas. Do not puncture or incinerate container. Do not mix this product with other chemicals.

DIRECTIONS FOR USE

Read the label before using

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

LOCATIONS OF USE: Disinfects and sanitizes cleanrooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device

and diagnostic manufacturing facilities. Use on hard non-porous, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain and stainless steel. It is compatible with non-porous hard surface materials.

HYPO-CHLOR 0.25% ®^{MC} is ready to use. Do not dilute. Hold container upright 15-30 cm (6-12 inches) from surface when applying.

DISINFECTION: Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with HYPO-CHLOR 0.25% ®^{MC} and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth wiper.

SANITIZATION: Thoroughly wet surface with HYPO-CHLOR 0.25% ®^{MC} and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes wipe dry with sterilized cloth wiper.

FUNGICIDAL: Thoroughly wet surface with HYPO-CHLOR 0.25% ®^{MC} and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth wiper.

Rinsing may be done with sterile water, if needed.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage: Store in a cool, dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

Disposal: Products or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. Follow Federal/Provincial/ State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

Container Handling: Non-refillable container. Do not reuse or refill this container to hold materials other than this product. Fill the container ¼ full with water and recap. Shake for 10 seconds and dispose of rinsate in sanitary sewer. Offer container for recycling if available or reconditioning if appropriate or place in trash.

Reorder #: vai xxabc, Rev mm/yy

5/5

User Information
Date Opened/Operator: <input type="text"/>
Expiration Date: <input type="text"/>
Area: <input type="text"/>

{Lot label on container}

LOT: xxxx {Date of manufacture is on Certificate of Analysis}

EXP: Day/month/year. {18 months} Once opened use within 90 days

Optional Label Claims:

HYPO-CHLOR 0.25% ®^{MC} is bactericidal. The results of AOAC Efficacy Tests show that HYPO-CHLOR 0.25% ®^{MC} is an effective hard surface disinfectant on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC#6538), and *Salmonella enterica* (ATCC#10708) in 10 minutes.

HYPO-CHLOR 0.25% ®^{MC} is an effective sanitizer on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in 5 minutes.

HYPO-CHLOR 0.25% ®^{MC} is an effective fungicide on inanimate, non-porous non-food contact surfaces demonstrated by the results of AOAC Efficacy Tests against *Trichophyton mentagrophytes* (ATCC# 9533) in 10 minutes.